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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,667	12/03/2001	Esteban Masuda	021044-000600US	7585

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/998,667

Applicant(s)

MASUDA ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6 and 9-47 is/are pending in the application.
- 4a) Of the above claim(s) 17,18 and 20-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 9-16, 19 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2006 has been entered.

Applicant's amendment of claims 1, 6 and 12 and the cancellation of claims 3-5, 7 and 8, in the paper of 1/10/2007, are acknowledged. Claims 1, 2, 6, 9-47 are still at issue and are present for examination.

Applicants' arguments filed on 1/10/2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 17, 18, 20-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in the paper of 9/28/2004. It is noted that applicants have used a status identifier of "withdrawn" for claim 19, which appears to be incorrect.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

\Claims 6 and 9 are indefinite in that it is unclear as to the meaning of "heterologous" in claim 6. This is due to the fact that in claim 6, applicants do not state what the referred to polypeptide is heterologous to and because claim 9, which is dependent from claim 6, further limits the claimed method such that the host cell is primary T lymphocyte, and the TRAC1 polypeptide of the claims, as originally recited in claim 1, is not heterologous to a primary T lymphocyte (i.e. does not naturally occur in a cell). Thus the meaning of "heterologous" in claim 6 is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 6, 9-16, 19 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applies to previous claims 1-16, 19 and 47. In response to this rejection, applicants have amended claims

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1, 6 and 12 and cancelled claims 3-5, 7 and 8 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that applicants have amended the claims to recite, in part, "a TRAC1 polypeptide, wherein the polypeptide comprises an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 1, wherein the TRAC1 polypeptide has ligase activity". Applicants submit that by virtue of this amendment the claims now read on a genus of polypeptides with 90% identity to the amino acid sequence of SEQ ID NO:1 with ligase activity and that these claims fully comply with the requirements of written description of a chemical genus.

Applicant's amendment of the claims and applicants complete argument is acknowledged and has been carefully considered, however continues to be found nonpersuasive for the reasons previously stated and repeated herein. While applicants amendment requiring additional structure of the claimed genus is acknowledged, a sufficient structure to function relationship has not been established to meet the requirements of the written description guidelines, because applicants amendment requiring that the claimed genus have "ligase activity" is not a sufficient functional limitation as there exist many different types of ligase activity, such that the skilled artisan would not recognize that applicants were in possession of a majority of the members of the claimed genus by virtue of this broad functional description.

Given the lack of additional representative species as encompassed by the claims, Applicants continue to have failed to sufficiently describe the claimed invention,

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in such full, clear, concise, and exact terms that a skilled artisan would recognize

Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 2, 6, 9-16, 19 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising contacting a compound (any small organic) with a TRAC1 polypeptide, wherein said TRAC1 polypeptide comprises the amino acid sequence of SEQ ID NO: 1 and determining the functional effect of the compound upon the TRAC1 polypeptide, does not reasonably provide enablement for any method comprising contacting a compound (any small organic) with any TRAC1 polypeptide comprising an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 1, having any ligase activity and determining any functional effect of the compound upon the TRAC1 polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applies to previous claims 1-16, 19 and 47. In response to this rejection, applicants have amended claims 1, 6 and 12 and cancelled claims 3-5, 7 and 8 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that applicants have amended the claims to recite, in part, "a TRAC1 polypeptide, wherein the polypeptide comprises an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 1, wherein the TRAC1 polypeptide has ligase activity". Applicants submit that these claims are fully enabled by the specification, as methods of determining percent identity and methods for determining ligase activity are known in the art and/or disclosed by applicant's specification. Thus given the high level of skill in the biotechnological arts, the skilled artisan could readily identify the encompassed TRAC1 polypeptides and practice the claimed methods without undue experimentation.

As above, applicant's amendment of the claims and applicants complete argument is acknowledged and has been carefully considered, however continues to be found nonpersuasive for the reasons previously stated and repeated herein. While applicants amendment requiring additional structure of the claimed genus is acknowledged, a sufficient structure to function relationship has not been established to enable the scope of applicants claimed invention, because applicants amendment requiring that the claimed genus have "ligase activity" is not a sufficient functional limitation, as there exist many different types of ligase activity, such that the skilled artisan would require undue experimentation to practice the methods of the claimed genus by virtue of this broad functional description.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any method comprising contacting a

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compound with any "any TRAC1 polypeptide comprising an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 1 and having any ligase activity, wherein said method involves determining any functional effect upon the TRAC1 polypeptide" and determining the functional effect of the compound upon the TRAC1 polypeptide. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those methods of use of those TRAC1 polypeptides, having the desired biological characteristics, is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13, 15, 16, 19 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Sitkovsky (U.S. Patent No. 5,180,662).

The rejection is stated in the previous office action as it applies to previous claims 1-4, 6-10, 13-16, 19 and 47. In response to this rejection, applicants have

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amended claims 1, 6 and 12 and cancelled claims 3-5, 7 and 8 and traverse the rejection as it applies to the newly amended claims.

Applicants disagree with the Examiner's interpretation of what is fairly disclosed by inherency from the teachings of Sitkovsky. Applicants submit that the examiner appears to suggest that the teachings in Sitkovsky would inherently anticipate any gene or polypeptide that is expressed in T lymphocytes and which is involved with T lymphocyte activation, whether or not the gene or polypeptide is known. Applicants submit that in order for a claim element to be anticipated by a prior art reference, "the missing descriptive material must be necessarily present in the thing described in the reference, and that it would be recognized by persons of ordinary skill". Applicants submit that the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Applicants submit that even if TRAC1 was expressed in the T lymphocytes described by Sitkovsky, the skilled artisan would have no way of recognizing this because TRAC1 is not disclosed by Sitkovsky, much less polypeptides with at least 90% identity. Even less readily recognizable is the fact that TRAC1 is involved in T lymphocyte activation.

Applicants submit that in order to expedite prosecution, applicants have further distinguished the claimed invention from the teachings of Sitkovsky by amending the claims to recite, in part, "determining the functional effect of the compound upon TRAC1 polypeptide activity" and that Sitkovsky can only be read to teach a method for

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measuring T-lymphocyte activation by measuring the secretion of granule-associated BLT esterase activity after treatment with activating stimuli and screening methods based on this activity. Thus Sitkovsky fails to teach or suggest methods for the screening of compounds that have an effect on TRAC1 polypeptide activity as is presently claimed.

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however continues to be found nonpersuasive for the reasons previously made of record and for those repeated herein.

With respect to applicants comments regarding what is fairly disclosed by inherency from the teachings of Sitkovsky, applicant is reminded that the methods taught by Sitkovsky anticipate the claimed methods. As previously stated, Sitkovsky teaches a method comprising contacting a compound with a "TRAC1 polypeptide", as defined by the limitations of the claim, and determining the "functional effect" of the compound upon the "TRAC1 polypeptide". It continues to be recognized that while Sitkovsky may or may not have been aware of the existence applicants disclosed "TRAC1 polypeptide", the methods taught by Sitkovsky anticipate the claimed methods. Sitkovsky specifically teaches a method for directly assaying cytotoxic T lymphocyte activation comprising: incubating cytotoxic T lymphocytes with one or more lymphocyte activating stimuli compound and measuring the secretion of said BLT-esterase resulting from the activation of cytotoxic T lymphocytes. The cytotoxic T lymphocytes of the method taught by Sitkovsky comprise a TRAC 1 polypeptide and thus incubating the T lymphocytes of Sitkovsky with the activating stimuli compound comprises contacting the

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compound with a TRAC1 polypeptide as claimed. Further, the method of Sitkovsky comprises the measurement of the secretion of BLT-esterase resulting from the activation of cytotoxic T lymphocytes, which is a functional effect of the compound upon TRAC1 polypeptide activity, as applicants specification teaches that TRAC1 is involved in T lymphocyte activation and thus BLT-esterase secretion is a functional effect of T lymphocyte activation or TRAC1 polypeptide activity..

It is admitted that Sitkovsky need not recognize the intermediate players involved in T lymphocyte activation, for Sitkovsky to anticipate the claimed methods.

With respect to applicants comments, that in order to expedite prosecution, applicants have further distinguished the claimed invention from the teachings of Sitkovsky by amending the claims to recite, in part, "determining the functional effect of the compound upon TRAC1 polypeptide activity" and that Sitkovsky can only be read to teach a method for measuring T-lymphocyte activation by measuring the secretion of granule-associated BLT esterase activity after treatment with activating stimuli and screening methods based on this activity, it is pointed out that the measurement of the secretion of granule-associated BLT esterase activity after treatment with T lymphocyte activating stimuli is considered to be a functional effect upon TRAC1 polypeptide activity as TRAC1 polypeptide modulates T lymphocyte activation.

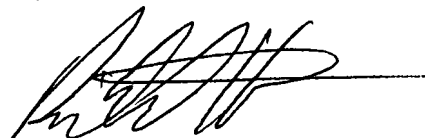
Thus claims 1, 2, 13, 15, 16, 19 and 47 remain anticipated by Sitkovsky for the reasons previously stated and repeated herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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5/9/2007